

5-9-05

PTO/SB/21 (09-04)

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Jury 6/14
\$**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number

10/016,146

Filing Date

December 10, 2001

First Named Inventor

Jay Cunningham

Art Unit

1614

Examiner Name

Phyllis G. Spivack

Attorney Docket Number

3078/04/US 31104/USA
(6794-000094/COC)**ENCLOSURES (check all that apply)**☒ Fee Transmittal Form☒ Fee Attached☐ Amendment / Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure
Statement☐ Certified Copy of Priority
Document(s)☐ Reply to Missing Parts/
Incomplete Application☐ Reply to Missing Parts
under 37 CFR 1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a
Provisional Application☐ Power of Attorney, Revocation
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) _____☐ Landscape Table on CD☐ After Allowance Communication to TC☐ Appeal Communication to Board
of Appeals and Interferences☐ Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s)
(please identify below):

Form HDP-1449

46 References

Return Receipt Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm

Harness, Dickey & Pierce, P.L.C.

Signature

Printed Name

Lydia N. Nenow

Date

May 6, 2005

Reg. No.

52,530

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

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Lydia N. Nenow

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Signature

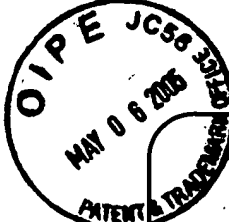
Date

May 6, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180

Complete If Known

Application Number	10/016,146
Filing Date	December 10, 2001
First Named Inventor	Jay Cunningham
Examiner Name	Phyllis G. Spivack
Art Unit	1614
Attorney Docket No.	3078/4/US

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money ☐ Other ☐ None
Order

☐ Deposit Account:

Deposit Account Number 08-0750

Deposit Account Name Harness, Dickey & Pierce, P.L.C.

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) or any underpayment of fees under 37 CFR 1.16 and 1.17
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1011	300	2011	150	Utility filing fee	
1012	200	2012	100	Design filing fee	
1013	200	2013	100	Plant filing fee	
1014	300	2014	150	Reissue filing fee	
1005	200	2005	100	Provisional filing fee	
SUBTOTAL (1)					(\$) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims		-20 **	=	0	X		= 0
Independent Claims		-3 **	=	0	X		= 0
Multiple Dependent							= 0

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	50	2202	25	Claims in excess of 20	
1201	200	2201	100	Independent claims in excess of 3	
1203	360	2203	180	Multiple dependent claim, if not paid	
1204	200	2204	100	** Reissue independent claims over original patent	
1205	50	2205	25	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	
1403	1000	2403	500	Request for oral hearing	
1452	500	2452	250	Petition to revive - unavoidable	
1453	1500	2453	750	Petition to revive - unintentional	
1501	1400	2501	700	Utility issue fee (or reissue)	
1502	800	2502	400	Design issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
Other fee (specify) _____					
*Reduced by Basic Filing Fee Paid					
SUBTOTAL (3)					(\$)180

4. SEARCH/EXAMINATION FEES

1111	500	2111	250	Utility Search Fee	
1112	100	2112	50	Design Search Fee	
1113	300	2113	150	Plant Search Fee	
1114	500	2114	250	Reissue Search Fee	
1311	200	2311	100	Utility Examination Fee	
1312	130	2312	65	Design Examination Fee	
1313	160	2313	80	Plant Examination Fee	
1314	600	2314	300	Reissue Examination Fee	
SUBTOTAL (4)					(\$)0

SUBMITTED BY		Complete (if applicable)	
Name (Print/Type)	Lydia N. Nenow	Registration No. (Attorney/Agent)	52,530
Signature		Telephone	314-726-7503
		Date	May 6, 2005

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EV 726255925 US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Jay Cunningham, et al.
Serial No: 10/016,146
Filed: December 10, 2001
Title: $\alpha_v\beta_3$ Integrin Antagonists in Combination with Chemotherapeutic Agents
Confirmation No: 7806
Group Art Unit: 1614
Examiner: Phyllis G. Spivack
Attorney Ref: 3078/US/04
Pfizer Ref: 31104/USA
HDP Ref: 6794-000094/COC

May 6, 2005

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam/Sir:

To comply with 37 C.F.R. §1.97 and §1.98, Applicants have enclosed Form 1449 and all references cited on that form with the exception of the U.S. patents. In accordance with MPEP §609 and §707.05(b), Applicants respectfully request that each document listed be given thorough consideration, and that the Examiner cite each document of record in the prosecution history of the present application by initialing the Form 1449 next to each document. Applicants request such initialing even if the Examiner does not consider: (1) a document to be sufficiently pertinent to use in a rejection; (2) a document to be prior art for any reason; or (3) that the guidelines for citation have been fully complied with respecting a particular document. Applicants make this request so that each document becomes cited on the face of a patent issuing on the present application.

Applicants submit this information disclosure statement in compliance with the duty to disclose information material to patentability under 37 CFR §1.56, but by listing such documents are not admitting that such documents are necessarily relevant or prior art.

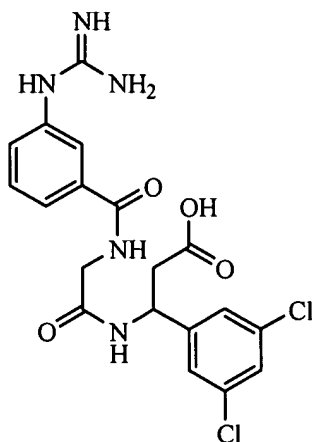
Applicants intend no representation that the listed documents represent the results of a

complete search. Applicants anticipate that the Examiner, in the normal course of examination, will make an independent search consistent with 37 CFR §1.104, and, in the course of such search, will review for relevance every document listed on the attached form even if not initialed.

This application is a continuation of U.S. Application Serial No. 09/262,725 (filed March 4, 1999, issued as U.S. Patent No. 6,372,719), which, in turn, is a continuation-in-part of U.S. Application Serial No. 09/034,270 (filed March 4, 1998, now abandoned). Applicants presume that the Examiner has access to the file histories for the above-referenced applications. Applicants further presume that the Examiner is aware of the issues raised and the scope of claims in those cases, and will take them into account when examining this patent application. Upon request from the Examiner, Applicants can provide copies of the substantive Office actions or any other information relating to those cases, to the extent Applicants have such information in their possession.

With respect to patent application publication DE 43 38 944 A1 (reference 15 in Form 1449), see patent application publication South Africa 94/9017 (reference 25 in Form 1449), which claims priority to DE 43 38 944, and is published in English.

The October 1, 2004 Office action requested the structure for the compound cited as "S448" in Nickols et al., "Antiangiogenic and anticancer activities of antagonists of integrin $\alpha_v\beta_3$ " published in Proceedings of the American Association of Cancer Research, Volume 38 (March 1997). It is Applicants' understanding that that compound corresponds in structure to the following formula:



Information Disclosure Statement
Appl. No. 10/016,146
May 6, 2005

Applicants request early and favorable consideration of this application.

* * * * *

Applicants have enclosed a check for \$180.00 to cover the fee for filing this supplemental information disclosure statement. Applicants do not believe that they owe any other fee in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge such fee(s) to Deposit Account No. **08-0750**. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or §1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **08-0750**.

The Examiner is requested to call the undersigned if any questions arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,



Lydia N. Nenow, PTO Reg. No. 52,530
Harness, Dickey & Pierce, P.L.C.
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St. Louis, Missouri 63105
(314) 726-7500 (tel)
(314) 726-7501 (fax)

Information Disclosure Statement
Appl. No. 10/016,146
May 6, 2005



CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I certify that this correspondence is being deposited with the U.S. Postal Service on **May 6, 2005** with sufficient postage as first class mail (including Express Mail per MPEP § 512), and addressed to **Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450**.

A handwritten signature in cursive script, appearing to read "Lydia N. Nenow".

Lydia N. Nenow

LNN/JPG/CML

FORM 1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Sheet 1 of 4

ATTORNEY DOCKET NO.

3078/4/US 31104/USA
(6794-000094/COC)

SERIAL NO.

10/016,146

APPLICANT

Cunningham, et al.

FILING DATE

December 10, 2001

GROUP

1614

U.S. PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1.		4,677,111	6/30/87	Haga, et al.	514/274	
2.		5,256,812	10/26/93	Alig, et al.	560/035	
3.		5,518,732	5/21/96	Sturzbecher, et al.	424/449	
4.		5,753,230	5/19/98	Brooks	424/158.1	
5.		5,766,591	6/16/98	Brooks	424/184.1	
6.		6,013,651	1/11/00	Rogers	514/269	

FOREIGN PATENT DOCUMENTS

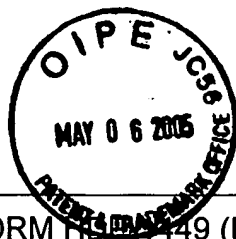
Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation	
						Yes	No
7.		AU-A-79090/94	6/8/95	Australia			
8.		AU-A-57984/94	10/6/94	Australia			
9.		2,059,857	7/25/92	Canada			
10.		2,134,418	4/29/95	Canada			
11.		EP 0 343 893 A1	11/29/89	EPO			
12.		EP 0 343 894 A1	11/29/89	EPO			
13.		EP 0 478 328 A1	4/1/92	EPO			
14.		EP 0 478 363 A2	4/1/92	EPO			
15.		DE 43 38 944 A1	5/18/95	Germany			X
16.		WO 95/32710	12/7/95	PCT			
17.		WO 98/31359	7/23/98	PCT			
18.		WO 95/28426	10/26/95	PCT			

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EV 726 255925 US



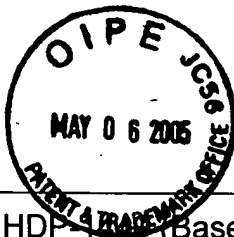
FORM PTO-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Sheet 2 of 4	ATTORNEY DOCKET NO.	SERIAL NO.
	3078/4/US 31104/USA (6794-000094/COC)	10/016,146
	APPLICANT	
	Cunningham, et al.	
	FILING DATE	GROUP
	December 10, 2001	1614

FOREIGN PATENT DOCUMENTS							
Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes	No
19.		WO 95/14714	6/1/95	PCT			
20.		WO 98/14192	4/9/98	PCT			
21.		WO 93/08823	5/13/93	PCT			
22.		WO 97/08145	3/6/97	PCT			
23.		WO 96/00730	1/11/96	PCT			
24.		WO 96/00574	1/11/96	PCT			
25.		94/9017	11/14/94	South Africa			
26.		94/2124	3/25/94	South Africa			
27.		94/0435	1/21/94	South Africa			

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
28.		Adamis, et al., Increased Vascular Endothelial Growth Factor Levels in the Vitreous of Eyes with Proliferative Diabetic Retinopathy, American Journal of Ophthalmology, Vol. 118 (1994) 445-450
29.		Brooks, et al., Integrin $\alpha_v\beta_3$ Antagonists Promote Tumor Regression by Inducing Apoptosis of Antiogenic Blood Vessels, Cell, Vol. 79 (1994) 1157-1164
30.		Brooks, et al., Requirement for Vascular Integrin $\alpha_v\beta_3$ for Angiogenesis, Science, Vol. 264 (1994) 569-571
31.		Carter, et al., Chemotherapy of Cancer, Sec. Ed., John Wiley & Sons, NY, NY (1981) 107-108
32.		Choi, et al., Inhibition of Neointimal Hyperplasia by Blocking $\alpha_v\beta_3$ Integrin with a Small Peptide Antagonist GpenGRDSPCA, Journal of Vascular Surgery, Vol. 19 (1) 125-134

Examiner:	Date Considered:
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EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM HDP-1 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Sheet 3 of 4

ATTORNEY DOCKET NO.	SERIAL No.
3078/4/US 31104/USA (6794-000094/COC)	10/016,146
APPLICANT	
Cunningham, et al.	
FILING DATE	GROUP
December 10, 2001	1614

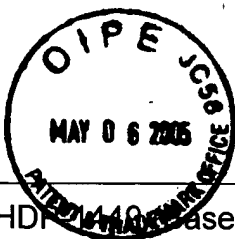
OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Ref. Desig.	Examiner's Initials	
33.		Clyman, et al., β_1 and β_3 Integrins Have Different Roles in the Adhesion and Migration of Vascular Smooth Muscle Cells on Extracellular Matrix, Experimental Cell Research, Vol. 200, (1992) 272-284
34.		Fields, Integrins: Cell Adhesion Molecules in Cancer, Exp. Opin. Ther. Patents, Vol. 8 (No. 6), (1998) 633-644
35.		Hong, et al., Discovery of HIV-1 Integrase Inhibitors by Pharmacophore Searching, J. Med. Chem., American Chemical Society, v. 40 (1997) 930-936
36.		Liaw, et al., The Adhesive and Migratory Effects of Osteopontin Are Mediated Via Distinct Cell Surface Integrins: Role of a $\alpha_v\beta_3$ in Smooth Muscle Migration to Osteopontin in Vitro, Journal of Clinical Investigation, Vol. 95 (1995) 713-724
37.		Derwent Abstract 1987-009150/198702
38.		Derwent Abstract 1987-065042/198710
39.		Derwent Abstract 1989-055466/198908
40.		Derwent Abstract 1989-349943/198948
41.		Derwent Abstract 1992-398070/199248
42.		Derwent Abstract 1993-060253/199308
43.		Derwent Abstract 1993-127579/199316
44.		Nicklaus, et al., HIV-1 Integrase Pharmacophore: Discovery of Inhibitors Through Three-Dimensional Database Searching, J. Med. Chem. v. 40 (1997) 920-929
45.		Peacock, et al., Angiogenesis Inhibition Suppresses Collagen Arthritis, Journal of Experimental Medicine, Vol. 175 (1992) 1135-1138
46.		Pommier, et al., HIV-1 Integrase as Target for Antiviral Drugs, Antiviral Chemistry & Chemotherapy, Vol. 8 (No. 6) (1997) 463-483
47.		Schnur, et al., N-(5-Fluorobenzothiazol-2-yl)-2-guanidinothiazone-4-carboxamide. A Novel, Systematically Active Antitumor Agent Effective Against 3LL Lewis Lung Carcinoma, Journal of Medicinal Chemistry, Vol. 34 (3) (1991) 914-918

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM HDP-1449 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Sheet 4 of 4

ATTORNEY DOCKET No.	SERIAL No.
3078/4/US 31104/USA (6794-000094/COC)	10/016,146
APPLICANT	
Cunningham, et al.	
FILING DATE	GROUP
December 10, 2001	1614

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Ref. Desig.	Examiner's Initials	
48.		Schnur, et al., Quantitative Structure-Activity Relationships of Antitumor Guanidinothiazolecarboxamides with Survival Enhancement for Therapy in the 3LL Lewis Lung Carcinoma Model, Journal of Medicinal Chemistry, Vol. 34 (7) (1991) 1975-1982
49.		Seftor, et al., Role of the $\alpha_v\beta_3$ Integrin in Human Melanoma Cell Invasion, Proceedings of the National Academy of Sciences U.S.A., Vol. 89 (1992) 1557-1561
50.		Smith, et al., Interactions of Integrins $\alpha_v\beta_3$ and GlycoProtein IIb-IIIa with Fibrinogen, Journal of Medicinal Chemistry, Vol. 265 (21) (1990) 12267-12271
51.		White, Integrins as Virus Receptors, Current Biology, Vol. 3 (9) (1993) 596-599
52.		Yue, Osteopontin-Stimulated Vascular Smooth Muscle Cell Migration is Mediated by $\alpha_v\beta_3$ Integrin, Experimental Cell Research, Vol. 214 (1994) 459-464

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.